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UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: BRIAN KEEGAN
Title: ANTHROPOMORPHIC PHANTOMS AND METHOD
Serial No: 10/800,956
Filing Date: MARCH 15, 2004
Group Art Unit: N/A
Attorney Docket No: KEEB 101
Date: May 27, 2004

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INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

In compliance with Applicant's and his attorney's duty of disclosure under 37 CFR 1.56, the Applicant does hereby submit the following Information Disclosure Statement, Form PTO - 1449, and copies of the references listed thereon.

A patent search was manually conducted for the invention described in the above-referenced patent application. In the course of the search, no patents were found for an apparatus that has the same structural features or that operates in the same manner such as the invention listed above. The following nine (9) patents, however, were noted as being of interest and are hereby brought to the Examiner's attention as references AA - AI. The significance of each listed reference is as follows:

1 AA. U.S. Patent No. 6,352,860 (Madsen et al.) discloses a tissue mimicking
2 material for ultrasound phantoms having ultrasound speed and attenuation characteristics that
3 are characteristic of human tissue and well suited for use in measuring and calibrating the
4 potential biological effects of ultrasound equipment. The material is formed of an aqueous
5 mixture of large organic water soluble molecules condensed from skim milk with a total
6 solids content in the range of 10% to 30% by weight. The total fat content is less than 1% by
7 weight, with the residual lipid particles of a size sufficiently small to remain in suspension
8 without agglomerating and separating from the mixture over extended periods of time.

9 AB. U.S. Patent No. 6,318,146 (Madsen et al.) discloses a tissue mimicking
10 material suitable for phantoms for use with at least ultrasound and MRI have sections of
11 material in contact with each other which mimic ultrasound and magnetic resonance imaging
12 properties of human tissues, and preferably also computed tomography properties, so that the
13 phantom can be used for the testing of imaging by various types of medical imagers. A
14 suitable tissue-mimicking material for use in phantoms of this type includes an aqueous
15 mixture of large organic water soluble molecules, a copper salt, a chelating agent for binding
16 the copper ions in the salt, and a gel-forming material. Small glass beads may be intermixed
17 therewith to provide a selected ultrasound attenuation coefficient without substantially
18 affecting the MRI properties of the material. Larger glass beads may be used in a section to
19 control primarily the ultrasound backscatter coefficient without significant effect on the
20 ultrasound attenuation coefficient. Tissue-mimicking material that simulates muscle may
21 have smaller glass beads and a higher concentration of gel-forming material than an adjacent
22 section. Such similar materials in contact with one another show relative stability over
23 extended periods of time.

1 AC. U.S. Patent No. 6,190,915 (Madsen et al.) discloses an improved ultrasound
2 phantom including a container having a window covered by an ultrasound transmitting
3 window cover that seals and protects a water based tissue mimicking material within the
4 container. The window cover includes a multi-layer film formed of at least a layer of metal
5 adhered to a layer of plastic. The metal layer is essentially impervious to moisture and air
6 molecules, preventing both desiccation of the water - based material within the phantom and
7 oxidation or contamination of the tissue mimicking material. Multiple windows may be
8 formed in the container, which are closed with the multi-layer film cover, and the container
9 may be formed entirely or partially as a flexible sack of multi-layer film.

10 AD. U.S. Patent No. 5,902,748 (Madsen et al.) discloses a tissue mimicking
11 material for use in ultrasound scanner phantoms that has a very low acoustic backscatter
12 coefficient. The tissue mimicking material has the ultrasonic speed and attenuation
13 characteristics of human tissue, with a backscatter coefficient of about 40 dB below that of
14 human liver tissue. The tissue mimicking material may be in liquid or solid form. A
15 component in both the liquid and solid forms is a filtered aqueous mixture of large organic
16 water - soluble molecules and emulsion of fatty acid esters. This mixture may be based on a
17 combination of evaporated whole milk and water. The material also includes a hydroxy
18 compound, such as n-propanol, to control the ultrasonic speed of propagation through the
19 material. A preservative from bacterial invasion, such as thimerosal, is also preferably
20 included in the material. The solid form of the material contains the same material as the
21 liquid form, with a very pure gel-forming material included to form a solid material. The
22 tissue mimicking material may be included in an ultrasound phantom container with solid
23 scattering particles and/or test objects incorporated therein. The use of scattering particles

1 allows a very broad range of relative backscatter levels to be achieved in ultrasound test
2 object phantoms incorporating the tissue mimicking material of the invention.

3 AE. U.S. Patent No. 5,625,137 (Madsen et al.) discloses a tissue mimicking
4 material for use in ultrasound scanner phantoms that has a very low acoustic backscatter
5 coefficient. The tissue mimicking material has the ultrasonic speed and attenuation
6 characteristics of human tissue, with a backscatter coefficient of about 40 dB below that of
7 human liver tissue. The tissue mimicking material may be in liquid or solid form. A
8 component in both the liquid and solid forms is a filtered aqueous mixture of large organic
9 water soluble molecules and emulsion of fatty acid esters. This mixture may be based on a
10 combination of evaporated whole milk and water. The material also includes a hydroxy
11 compound, such as n-propanol, to control the ultrasonic speed of propagation through the
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13 included in the material. The solid form of the material contains the same material as the
14 liquid form, with a very pure gel-forming material included to form a solid material. The
15 tissue mimicking material may be included in an ultrasound phantom container with solid
16 scattering particles and/or test objects incorporated therein. The use of scattering particles
17 allows a very broad range of relative backscatter levels to be achieved in ultrasound test
18 object phantoms incorporating the tissue mimicking material of the invention.

19 AF. U.S. Patent No 5,061,187 (Jerath) discloses a medical ultrasound training
20 apparatus comprising a simulated body cavity adapted to contain a number of elements
21 simulating the ultrasonic response characteristics of internal human anatomy. Simulated body
22 fluid fills the cavity and surrounds and suspends the elements therein and a skin simulating
23 membrane covers the cavity. A medical trainee performs ultrasound examination on the

1 apparatus which produces ultrasound images similar to those produced by a live patient
2 thereby providing the trainee with valuable experience in applying and analyzing the results
3 of the ultrasound examination.

4 AG. U.S. Patent No. 4,974,461 (Smith et al.) discloses an apparatus and method for
5 producing ultrasound readings of simulated blood flow through a model left ventricle or
6 larger portion of the human heart, held inside a fluid filled chamber with membrane-covered
7 windows, and through mitral and aortic valves cooperating therewith to provide a simulated
8 human circulation flow free of reverberation artifacts and the like. Adjustable flow of a
9 selected hydraulic fluid into and out of the chamber that also contains a plurality of
10 ultrasound absorbing elements disposed oppositely to the ultrasound viewing windows is
11 utilized to produce ultrasound signals picked up by an ultrasound transducer for processing in
12 any known manner. A range of flow rate and systolic characteristics of a heart are readily
13 simulated, to provide outputs substantially free of reverberations and ultrasound reflections
14 from the inside walls of the chamber as well as the ultrasound absorbing elements.

15 AH. U.S. Patent No. 4,286,455 (Ophir et al.) discloses an ultrasound phantom
16 which has ultrasound wave velocities, attenuation coefficients and scattering coefficients
17 which closely mimic those of human tissue and which permits diagnostic ultrasound
18 equipment to be accurately tested and calibrated on a continuing day-to-day basis. The
19 phantom preferably includes a substantially air-tight enclosure or box, having therein a
20 quantity of reticulated synthetic resin foam material and a salt water solution. The ultrasonic
21 characteristics of the phantom are completely uniform, stable and reproduceable, can be
22 varied at will by using different foam materials and/or liquids, and the phantom can be stored
23 and used at room temperature without degradation thereof. Localized zones having different

1 ultrasonic qualities for mimicking various normal and pathological tissues can also be
2 provided by hollowed, cut-out regions within the foam material, with different inserts located
3 within certain of the hollowed regions.

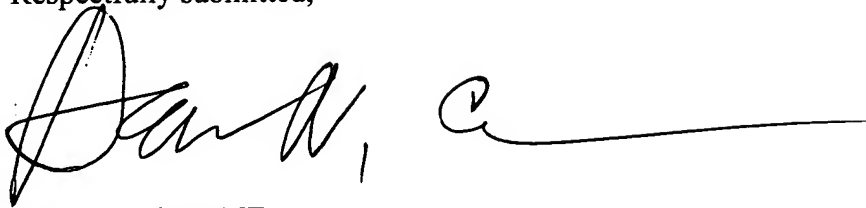
4 AI. U.S. Patent No. 4,277,367 (Madsen et al.) discloses a tissue mimicking
5 material for use in ultrasound phantoms formulated as a uniform suspension of solid particles
6 of graphite, talc, pumice, polyethylene microspheres, or liquid particles of vegetable oils,
7 kerosine, or combinations thereof described as scatterers in a congealed gelatin-water-
8 alcohol-preservative matrix; containing detergents to create the liquid particles.

9 The Applicant and his attorney submit that the above-cited references taken alone or
10 in combination neither anticipate nor render obvious the present invention. None of the
11 references disclose or claim an anthropomorphic phantom for use with ultrasonic imaging
12 procedure training, comprising a phantom body made of a chemical composition capable of
13 being heated and poured into a primary mold to form a simulated human anatomical
14 structure, said chemical composition when cooled to room temperature being self-sealing
15 when punctured with a scattering agent suspended into said chemical composition to simulate
16 the sonographic characteristics of a human anatomical structure; and, at least one blood
17 vessel simulating conduit formed inside said phantom body.

18 The listed references relate only to the general field of the disclosure and do not
19 constitute an admission that the references are relevant or material to the claims; they are
20 cited only as constituting the closest art of which the Applicant and his attorney are aware.

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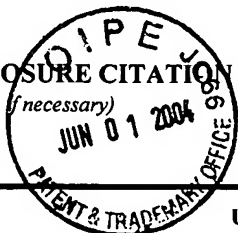
Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Dean A. Craine', followed by a long horizontal line extending to the right.

DEAN A. CRAINE

Reg. No. 33,591

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>	Docket Number (Optional) KEEB 101	Application Number 10/800,956
	Applicant(s) BRIAN KEEGAN	
	Filing Date MARCH 15, 2004	Group Art Unit N/A



U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA.	6,352,860	03/05/2002	MADSEN ET AL.	436	8	11/17/2000
	AB.	6,318,146	11/20/2001	MADSEN ET AL.	73	1.86	07/14/1999
	AC.	6,190,915	02/20/2001	MADSEN ET AL.	436	8	06/25/1999
	AD.	5,902,748	05/11/1999	MADSEN ET AL.	436	8	08/06/1996
	AE.	5,625,137	04/29/1997	MADSEN ET AL.	73	1.84	05/25/1995

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(Use several sheets if necessary)

OF

CERTIFICATE OF MAILING BY FIRST CLASS MAIL (37 CFR 1.8)Applicant(s): **BRIAN KEEGAN**

Docket No.

KEEB 101Application No.
10/800,956Filing Date
MARCH 15, 2004Examiner
N/ACustomer No.
N/AGroup Art Unit
N/A

Invention:

ANTHROPOMORPHIC PHANTOMS AND METHODI hereby certify that this **INFORMATION DISCLOSURE STATEMENT**

(Identify type of correspondence)

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on **MAY 28, 2004**
(Date)**DEAN A. CRAINE**

(Typed or Printed Name of Person Mailing Correspondence)

(Signature of Person Mailing Correspondence)

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